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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/930,877	08/15/2001	Brian Zambrowicz	LEX-0220-USA	1813

24231 7590 03/12/2004

LEXICON GENETICS INCORPORATED  
8800 TECHNOLOGY FOREST PLACE  
THE WOODLANDS, TX 77381-1160

EXAMINER

WHITEMAN, BRIAN A

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 03/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/930,877

Applicant(s)

ZAMBROWICZ ET AL.

Examiner

Brian Whiteman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/23/03.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### **Final Rejection**

Claims 5-7 are pending.

Applicants' traversal and the amendment to claims 5-7 and the cancellation of claims 1-4 in paper filed on 12/23/03 is acknowledged and considered.

### ***Election/Restrictions***

The gene targeted animal in claims 5-7 remains withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in paper filed on 4/29/03.

### ***Specification***

The disclosure remains objected to because of the following informalities: the status (pending, abandoned, US Patent) of each U.S. application cited on pages 5, 10, and 12 in the specification is missing.

Applicants did not address this objection.

Appropriate correction is required.

### ***Claim Objections***

Claim 5 remains objected to because of the following informalities: Claim 5 still reads on a non-elected invention (gene targeted animal).

Applicant's arguments argue that, "Amended claim 5 clearly recites that it claims a process for producing a gene targeted animal cell, etc. and thus the objection to claim 5 is deemed to have been avoided by amendment." See page 3.

Applicants' arguments filed 12/23/03 have been fully considered but they are not persuasive because the claim clearly recites: A process of generating **a gene targeted animal or cell** and still reads on a non-elected invention.

Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 5-7 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5-7 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite because the claims do not define what the process is nor what is used in the process. The claims do not define whether a clone obtained from a collection of genomic DNA clones or a vector comprising said clone and a marker sequence is used in the process. If the clone is present in a vector, then the claims do not define whether the clone is obtained from a solid support matrix or from another source (e.g., isolated from a cell or a plasmid).

Applicant's argue, "those skilled in the art would clearly understand that claims recites that the genomic clones are present in a vector and that the combination has been placed into

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individual wells of a microtiterplate (which serves as a source of clone “stock” for subsequent use and manipulation).” “Amended Claim 5 also recites that the claimed process requires the use of a genomic clone that has come from a collection of genomic DNA clones that have undergone the steps of being individually isolated and arrayed into wells of a microtiterplate.” See page 3.

Applicant's arguments filed 12/23/03 have been fully considered but they are not persuasive because the claims are still do not define what the process is nor what is used in the process. The only amendment to the claims is that the clones were isolated and arrayed into wells of a microtiter plate instead of a solid support matrix. This amendment does not address the 112 second paragraph rejection.

In addition, with respect to applicants' assertion, the assertion is not persuasive because the other than the assertion the applicants do not provide any evidence of record to support the assertion. See MPEP § 716.01(c).

Claims 5-7 remain rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: active steps for completing the process. The claims are directed to a process, but the claims have no active process step(s).

Applicant's arguments filed 12/23/03 have been fully considered but they are not persuasive because the claims are still missing the active steps for the completing the process.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 5 and 6 are rejected under 35 U.S.C. 102(e) as being anticipated by Thukral (US 6,503,712). Thukral teaches a method for producing gene-targeting constructs by homologous recombination using clones obtained from mouse genomic libraries arrayed in yeast shuttle vectors, wherein the constructs have a negative marker selectable in mammalian embryonic stem cells (abstract and columns 5-10). The clones are saved in microtiter plates (columns 13-14).

Claims 5 and 6 are rejected under 35 U.S.C. 102(e) as being anticipated by Tartaglia et al., (US 5,972,621). Tartaglia teaches producing a gene-targeting cell using clones in vectors and modifying the clones of genomic DNA using homologous recombination (columns 9, 13, and 51-52). Tartaglia teaches that vectors can comprise a negative marker in ES cells (columns 44 and 45). Tartaglia teaches that the clones are picked and arrayed in microtiter plates (columns 51-52)

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Thukral (US 6,503,712) or Tartaglia et al., (US 5,972,621) taken with Bogosian (US 5,932,439).

Tartaglia teaches producing a gene-targeting cell using clones in vectors and modifying the clones of genomic DNA using homologous recombination (columns 9, 13, and 51-52).

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Tartaglai teaches that vectors can comprise a negative marker in ES cells (columns 44 and 45).

Tartaglai teaches that the clones are picked and arrayed in microtiter plates (columns 51-52)

Thukral teaches a method for producing gene-targeting constructs by homologous recombination using clones obtained from mouse genomic libraries arrayed in yeast shuttle vectors, wherein the constructs have a negative marker selectable in mammalian embryonic stem cells (abstract and columns 5-10). The clones are saved in microtiter plates (columns 13-14).

However, neither Thukral nor Tartgali teaches using transposition to modify said clone.

However, at the time the invention was made, Bogosian teaches that homologous recombination and transposon mutagenesis are conventional methods to manipulate or mutate a gene (column 6).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of either Thukral or Tartaglia taken with Bogosian to modify the clone by transposon mutagenesis. One of ordinary skill in the art would have been motivated to modify the clone by transposition because Bogosian teaches that modifying a gene by transposon mutagenesis is routine method for one of ordinary skill in the art.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.



***Response to Arguments***

Applicant's arguments, filed 12/23/03, with respect to claim objection have been fully considered and are persuasive. The objection of claims 6 and 7 has been withdrawn because of the amendment -- The process according to claim 5 --.

Applicant's arguments, filed 12/23/03, with respect to 102(e) rejection over Westphal have been fully considered and are persuasive because Westphal does not teach clones isolated and arrayed into wells of a microtiter plate. The rejection of claims 5-7 has been withdrawn.

Applicant's arguments, filed 12/23/03, with respect to 102(b) rejection over Nehls have been fully considered and are persuasive because Nehls does not teach clones isolated and arrayed into wells of a microtiter plate. The rejection of claims 5 and 6 has been withdrawn.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

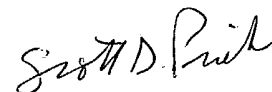
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, SPE - Art Unit 1635, can be reached at (571) 272-0760.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Brian Whiteman  
Patent Examiner, Group 1635



SCOTT D. PRIEBE, PH.D  
PRIMARY EXAMINER